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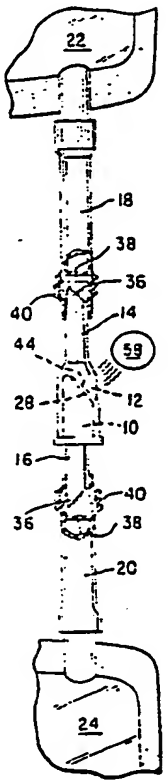
(54) Title: ONE-PIECE CONNECTOR MEMBERS AND STERILE CONNECTOR SYSTEM

(57) Abstract

A sterile connector system has first and second connector members (10, 12), each comprising a hollow housing (26, 42) and a port (14, 16) for flow communication to and from each hollow housing. One of the connectors (10, 12) is opaque and the other transparent, both being made of thermoplastic material, with at least a portion of transparent, thermoplastic wall of one of the connector members being positioned adjacent to and along the opaque, thermoplastic wall of the other of the connectors. Typically, both connector members are tubular in form, with the opaque connector (10) fitting inside of the transparent connector (12) in telescoping relation. Accordingly, radiant energy can melt at least a part of the opaque wall (28) by absorption, and at least a part of the transparent wall (44) can correspondingly melt primarily by heat conduction from the opaque wall, to cause a hole to open between the two walls and fusion of the materials of the wall together.



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Description

One-Piece Connector Members And Sterile Connector System

Technical Field

In particularly the field of blood handling and the administration of parenteral solution, it is desirable to be able to make sterile transfer of blood or parenteral solution from one container to another. For example, one may wish to use part of a unit of blood, while being able to continue to store the remaining portion on a long-term basis. Also, one may desire to mix two different parenteral solutions without any compromising of sterility, which requires immediate use of the material, for example by mixing a glucose solution with an amino acid hydrolysate solution for total parenteral nutrition.

Background Art

Granzow et al. U.S. Patent No. 4,157,723 discloses a sterile connector system in which two connector members are locked together, preferably with opaque, thermoplastic wall portions being carried on a conduit about their periphery by transparent wall portions of the conduit. The opaque wall portions are brought together into facing contact, and then exposed to sufficient radiant energy to cause the opaque wall portions to fuse together to open an aperture through the fused wall portions, to provide sealed communication between the interiors of the conduits. This may be a sterile connection, particularly when the opaque, thermoplastic wall portion has a high melting range of over essentially 200°C.

Additionally, Ammann et al. U.S. Application Serial No. 005,749, filed January 23, 1979, and Boggs et al. Application Serial No. 27,575, filed April 6, 1979 dis-

close further improvements on the sterile connector system of the type disclosed in the patent cited above.

Furthermore, Bellamy et al. Application Serial No. 091,688, filed November 5, 1979, discloses sterile connector systems connected to vials or flexible bags, with the type of sterile connector being similar to the previously-cited patent applications. The sterile connector preferably has auxiliary sealing means, which may be opened from the exterior in a manual way without breach of sterility.

The type of sterile connector systems described in the patent and applications cited above makes practical the long-felt need of providing a highly reliable sterile transfer of materials between various containers, so that, as stated above, partial units of blood may be used and the remainder sent back to storage, and other sterile solutions which are particularly subject to growth of bacteria upon contamination may be entered without the requirement for immediate use of the entire unit of sterile material.

By this invention, a substantial simplification and improvement in sterile connectors is provided in which the broad, overall principle of the above-cited patent is utilized, with the improvement resulting in a major reduction in the cost of sterile connectors in accordance with this invention, since they may be each molded out of a single piece of thermoplastic material. Furthermore, an overall simplification of the manufacturing operation is also achieved, for a significant advance in the design of sterile connectors, while still obtaining the desired capability for reliable sterile entry into containers without compromise of sterility.

Summary of the Invention

In accordance with this invention a sterile connector system is provided which comprises a first connector

member defining a first, hollow housing having an opaque, thermoplastic wall, and a first port for flow communication to and from the first hollow housing.

A second connector member defines a second hollow housing having a transparent, thermoplastic wall, the transparent wall being capable of being positioned adjacent to and along the opaque wall, and a second port for flow communication to and from the second hollow housing.

Means are provided in the hollow housings permitting the application of radiant energy to the adjacently-positioned opaque wall and transparent wall, to melt at least a portion of the opaque wall by absorption of radiant energy applied, and also to melt at least a portion of the transparent wall primarily by heat conduction from the opaque wall, to cause a hole to open between the two walls and fusion of the materials of the walls together.

Preferably, each of the first and second connector members may be single, molded pieces of thermoplastic, for great simplification of manufacture and reduction of cost, with the first hollow housing being made of an opaque, thermoplastic material and the second hollow housing being of a transparent, thermoplastic material. Typically, the radiant energy is directed through the second transparent hollow housing to impinge and be absorbed by the first hollow housing, so that heat is generated in the opaque wall of the first hollow housing by absorption of the radiation, which heat is then transferred by conduction to the transparent wall through which the radiation passes, to cause both of them to fuse together and to open a hole between them in a manner similar to the technique described in the previously-cited patent.

Each of the first and second ports of the hollow housings are preferably in sealed flow communication with

first and second containers, for the sterile retention and also sterile transfer of materials.

It is also generally preferred for the first hollow housing to be tubular in shape and to have an opaque, thermoplastic end wall. The second hollow housing is also preferably tubular, and is transparent, as stated above, having an open end and defining an interior, transparent thermoplastic wall across the bore thereof. The second port for flow communication to and from the second hollow housing may be at a position separated from the open end of the second, hollow, transparent tubular housing by the interior, transparent wall.

For connection, the first housing is telescopically inserted through the open end into the bore of the second housing, with the opaque end wall and the interior, transparent wall of the respective housings being positioned together in adjacent, facing relation to each other within the second housing.

The radiant energy may be applied to pass through the wall of the transparent second housing, to impinge on the opaque end wall in sufficient intensity to heat it to the melting point. As before, the heat is transferred to the interior, transparent wall primarily by conduction, so that the two walls fuse together and open an aperture for sterile connection.

It is generally preferable for the materials of the first and second connector members of this invention to be made of a substantially crystalline material such as poly (4-methyl-1-pentene), sold under the trademark TPX by Mitsui Chemical Company, or other materials as described in the Boggs et al. application cited above. The preferred substantially crystalline materials exhibit melting points above essentially 200°C. so that sterilization of their surfaces takes place as the melting is

effected, so that the newly opened hole between the two walls spontaneously provides a sterile surface as it is formed. At the same time, the two walls fuse together so that a sealed aperture is formed between the two walls, with the surface being sterile because of the high temperatures encountered during the fusing and hole-opening step.

It is preferred for the opaque end wall and interior, transparent wall of the first and second connector members to be inclined at an acute angle to the axes of the first and second housing, the angle being typically 30° to 60°. This permits the two walls which are to be melted to be more conveniently exposed to irradiation through the transparent, outer wall of the second connector member.

It is also preferable for each housing to define one member of key and keyway means, to interact together to prevent relative rotation thereof. Likewise, the first and second connector members, when in tubular form, may be tapered to cooperatively define a luer-type seal therebetween for added sealing and mechanical support of the connector structure, above and beyond the sterile sealing which is provided by the fusion of the opaque end wall and interior, transparent wall.

Brief Description of the Drawings

Figure 1 is a partly schematic elevational view of the sterile connector system of this invention, connected to a pair of sealed collapsible containers, taken partly in section.

Figure 2 is a plan view of the first, opaque connector member of this invention.

Figure 3 is a longitudinal sectional view of the structure of Figure 2, but rotated 90° about its longitudinal axis.

Figure 4 is a plan view of the second, transparent connector member of this invention.

Figure 5 is a longitudinal sectional view of the structure of Figure 4, but rotated 90° about its longitudinal axis.

Figure 6 is a longitudinal sectional view of the connected first and second connector members of Figure 1.

Description of Specific Embodiment

Referring to the drawings, Figure 1 shows a connector system of joined first connector member 10 and second connector member 12. Each of the connector members is connected respectively to first and second ports 14, 16 which, in turn, are each connected to flexible plastic tubing 18, 20, in sealed manner, which is joined to containers for the sterile retention of various contents, for example collapsible plastic bags 22, 24.

Bags 22, 24 may be blood bags, as part of single or multiple blood bag systems for the collection and/or storage of blood and its various components such as plasma, packed red cells, platelets, or while cells. Alternatively, bags 22, 24 may contain respective materials for mixing, for example lyophilized medication in one bag and a carbohydrate solution in the other for total parenteral nutrition, or any other material for which sterile retention after mixing or transfer from one container to another is desired.

In the alternative, one or more of the containers 22, 24 may be a rigid or semi-rigid vial of a design and for purposes similar to that shown in the previously cited Bellamy et al. patent.

In brief, the connector system of this invention may be used for any prupose where it is desired to transfer the contents of one container to another for mixing or

separation of components or the like, with reliable maintenance of sterility during and after the transfer.

The first connector member 10 is shown in detail in Figures 2 and 3. Preferably, connector 10 may be a single, molded piece of TPX thermoplastic, sold by the Mitsui Chemical Company and filled for example with powdered charcoal, carbon black, or the like to render it opaque as described in the previously-cited Boggs et al. application.

First connector member 10 comprises a first hollow tubular housing 26 having an opaque, thermoplastic end wall 28 as an integral part thereof. First port 16 is also provided for communication to and from hollow housing 26, being sealed to tubing 20 for aseptic communication with bag 24.

Flanges 32 and 33 are provided to facilitate the manual insertion of first connector member 10 into second connector member 12, and to also aid positioning of the membrane for sealing.

Additionally, first connector 10 may carry a longitudinally disposed key member 34 to fit into a keyway defined in second connector 12, to assist in the retention of the two housings together until the respective opaque end wall and interior transparent wall are fused together, and also to prevent relative rotation of the connector members 10, 12.

If desired, as shown, the end of port 16 may define a pointed spike 36 for manual penetration of diaphragm 38 by the collapsing of bellows 40, to provide an auxiliary sealing device, for example as shown in the copending Dossin application Serial No. 196,966, filed October 14, 1980.

Referring to Figures 4 and 5, second connector member 12 is shown, also defining a hollow housing 42.

Second connector member 12 may also be an integrally molded single piece of thermoplastic material, for example made of the same TPX thermoplastic but free of opaque filler so that housing 42 is transparent.

Interior transparent thermoplastic wall 44 is defined across the bore of second connector member 12. Second port 14 is defined, sealed to tubing 18 and separated from the open end 46 of second connector 12 by interior transparent wall 44, so that the entire interior area of tubing 18 and port 56 may be retained in sterile manner as long as wall 44 remains intact.

Second connector 12 defines on its exterior a keyway 48, sealed from the exterior by an outer wall 50. Keyway 48 is adapted to receive key member 34 in tight, gripping relation in area 52, to assist in the retention of the two members 10, 12 together and also to prevent rotation. The outer portion of keyway 48 is flared outwardly for ease of assembly, to receive key member 34 as first connector 10 is manually thrust into second connector 12, and to direct key member 34 into the tight portion 52 of the keyway 48.

As is the case with respect to housing 10, port 14 of housing 12 may optionally also carry a spike member 36 at its end, enclosed by a boot member 40, so that diaphragm 38 may be penetrated as desired by the manual manipulation of spike 36 and longitudinally collapsible boot member 40.

Accordingly, in use, as connector member 10, 12 are brought together by inserting connector member 10 into connector member 12, opaque end wall 28 and interior transparent wall 44 are brought into proximate, overlying relationship and preferably in essentially substantially abutting relationship. At the same time, connector member 10 may be slightly tapered in area 54 to

match a corresponding taper in area 56 of connector member 12, so that the two connector members fit together in a luer-type sealing relationship for added sealing benefit, with the interaction of key 34 and keyway 48 providing a nonrotatable relationship.

The assembled connectors 10, 12 may then be exposed to a source of strong light 58, or other radiation such as infrared radiation, focused through a lens if desired, and directed through the outer wall of second housing 12 and interior wall 44, to impinge upon opaque end wall 28 and be absorbed thereby.

The intensity of the radiation utilized should be sufficient to provide enought energy to heat opaque end wall 28 into its melting range which, as previously stated, is preferably in excess of 200°C. to obtain sterilizing action. Membrane 44 is correspondingly heated, primarily by conduction of the heat from end wall 28, but also possibly by some direct absorption of radiation, although interior wall 44 is substantially transparent.

As a result of this, the two walls 28, 44 fuse together, and a hole is opened between them, with microorganisms existing on the outer surface of the walls being encapsulated in the molten plastic material and killed by the heat, as in Figure 6.

The radiation is then turned off, and the plastic walls 28, 44 are allowed to cool and resolidify, fused together in a bond which may be of improved strength over the fused, opaque walls of the prior art where both of the walls are opaque, to provide a sterile, newly-opened connection between the two connectors 10, 12. After this, the respective diaphragms 38 may be broken by the collapsing of boot members 40, for penetration by spikes 36, providing the fully-opened, sterile connection between bags 22 and 24.

If desired, first connector 10 may also be transparent, with an opaque layer carried on end wall 28. For example, a layer of ink, plastic or paint may be painted, sprayed or printed onto end wall 28, to yield results equivalent to those described above.

The above has been offered for illustrative purposes only, and is not intended to limit the scope of the invention of this application, which is as defined in the claims below.

That Which is Claimed is:

1. A sterile connector system, which comprises: a first connector member defining a first hollow housing having an opaque, thermoplastic wall, and a first port for flow communication to and from said first hollow housing; a second connector member defining a second hollow housing, a transparent thermoplastic wall, said transparent wall being positioned adjacent to and along said opaque wall, and a second port for flow communication to and from said second hollow housing; and means permitting the application of radiant energy to said adjacently-positioned opaque wall and transparent wall to melt at least a portion of said opaque wall by absorption of said radiant energy and to melt at least a portion of said transparent wall substantially by heat conduction from said opaque wall, to cause a hole to open between the two walls and fusion of the materials of the walls together.

2. The sterile connector system of Claim 1 in which said first and second ports are in sealed flow communication with first and second containers for the sterile retention of materials.

3. A sterile connector system which comprises: a first connector member defining a first hollow tubular housing having an opaque, thermoplastic end wall and a first port for flow communication to and from said first hollow housing; a second hollow, transparent, tubular housing having an open end defining an interior, transparent thermoplastic wall across the bore thereof and spaced from the ends thereof, and a second port for flow communcation to and from said second, hollow housing at a position separated from said open end by the interior,

transparent wall; said first housing being telescopically inserted through said open end into the bore of the second housing, with the opaque end wall and interior transparent wall positioned together in adjacent, facing relation to each other, whereby radiant energy passing through said second, transparent housing can melt at least a portion of said opaque wall by absorption of said radiant energy and to melt at least a portion of said transparent wall substantially by heat conduction from said opaque wall, to cause a hole to open between the two walls and fusion of the materials of the walls together.

4. The sterile connector system of Claim 3 in which said first and second ports are in sealed flow communication with first and second containers for the sterile retention of materials.

5. The sterile connector system of Claim 4 in which said first housing and opaque end wall define a single molded piece of opaque thermoplastic.

6. The sterile connector system of Claim 5 in which said second housing and interior wall define a single molded piece of transparent thermoplastic.

7. The sterile connector system of Claim 6 in which said opaque end wall and interior transparent wall are each inclined at a similar angle of 30° to 60° to the axes of said first and second housings.

8. The sterile connector system of Claim 7 in which each housing defines one member of key and keyway means to interact together to prevent relative rotation thereof.

9. The sterile connector system of Claim 3 in which said first and second connector members are tapered to cooperatively form a luer-type seal therebetween.

10. A connector member for a sterile connector system which comprises a hollow, tubular housing having an opaque, thermoplastic end wall and a port for flow communication to and from said hollow housing, said opaque thermoplastic end wall being inclined at an acute angle to the axis of said tubular housing, and a member of key and keyway means carried by said first housing positioned to fit into another member of the key and keyway means of a second tubular housing into which said first housing penetrates to prevent relative rotation thereof.

11. The connector member of Claim 10 in which said port is connected to tubing in sealed flow communication with a container for the sterile retention of materials.

12. The connector member of Claim 10 which is made from a single, molded piece of thermoplastic.

13. A connector member for a sterile connector system which comprises a hollow, tubular transparent housing having an open end and defining an interior, transparent thermoplastic wall positioned across the bore and spaced from the ends thereof, said housing also defining a port for flow communication to and from said housing at a position separated from said open end by the interior transparent wall, said interior transparent wall being inclined at an acute angle to the axis of said housing.

14. The connector member of Claim 13 in which a member of key and keyway means is carried by said housing

and positioned to fit another member of key and keyway means of another tubular housing.

15. The connector member of Claim 14 which is made from a single, molded piece of thermoplastic.

16. The connector member of Claim 15 in which said port is connected in sealed flow communication with a container for the sterile retention of materials.

17. The connector member of Claim 16 in which said port defines a sharpened outer end, a bellows member being attached to said port member, and a diaphragm means blocking flow through said tubing, said diaphragm being positioned to be penetrated by the pointed end upon manual collapse of the bellows member.

18. The connector member of Claim 10 in which said port defines a sharpened outer end, a bellows member being attached to said port member, and a diaphragm means blocking flow through said tubing, said diaphragm being positioned to be penetrated by the pointed end upon manual collapse of the bellows member.

FIG. 1

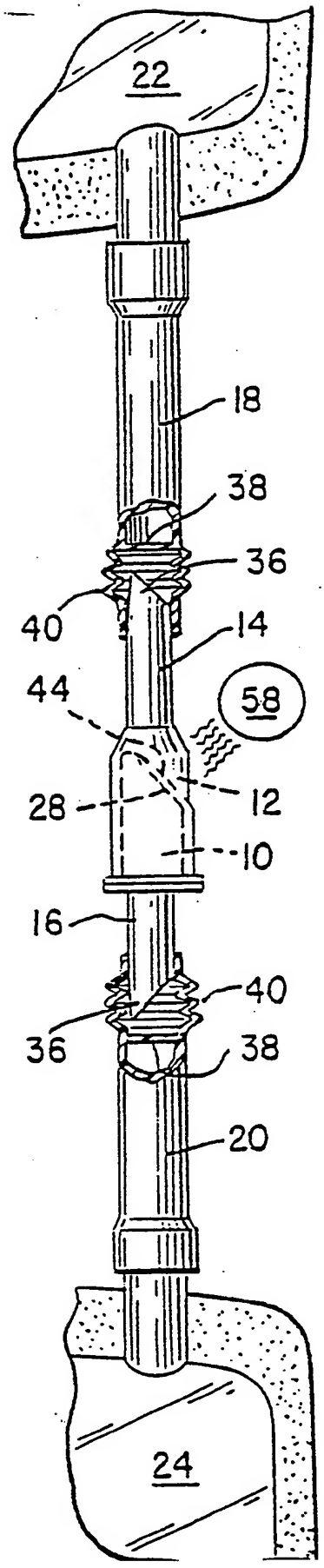
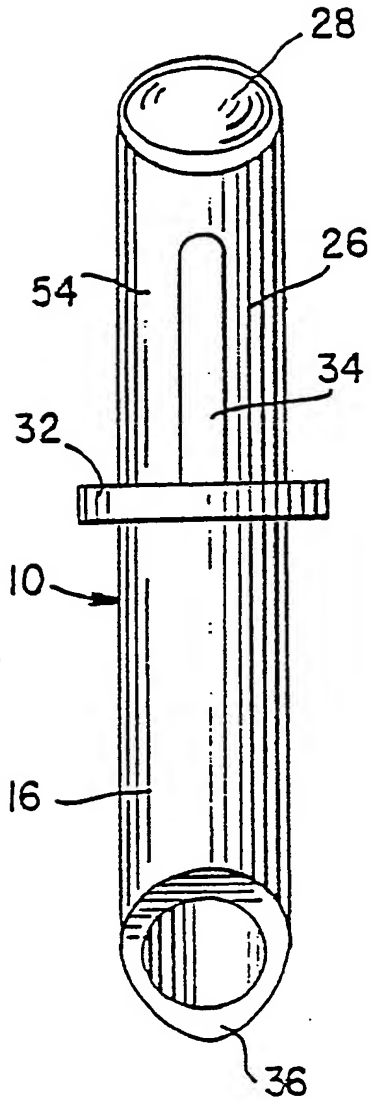


FIG. 2



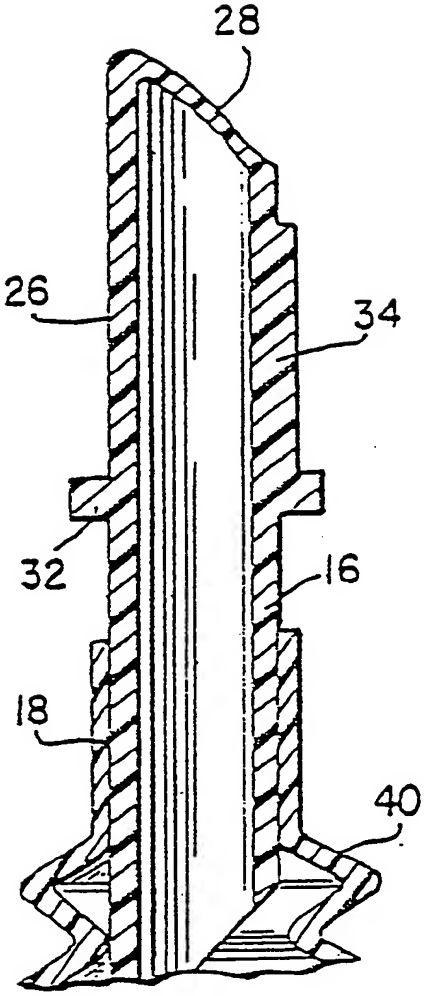


FIG. 3

FIG. 4

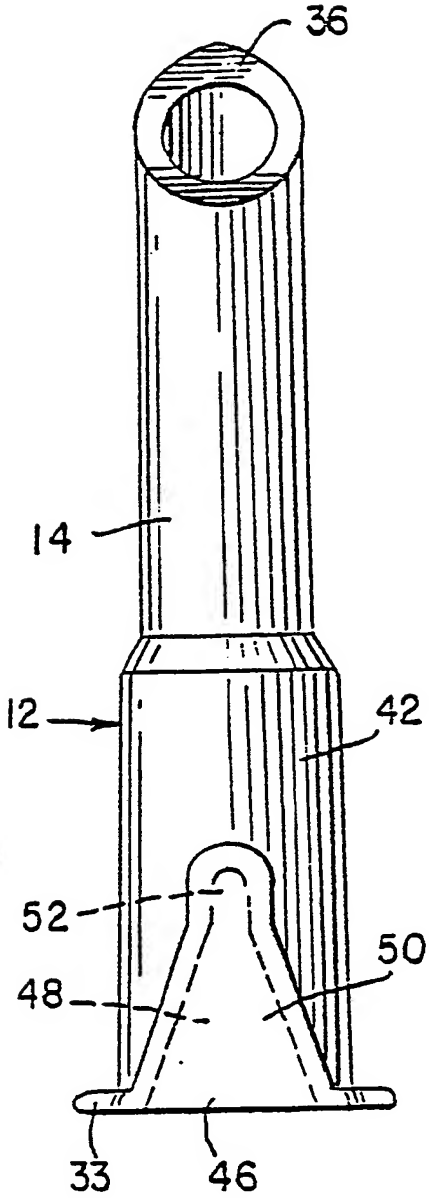


FIG. 5

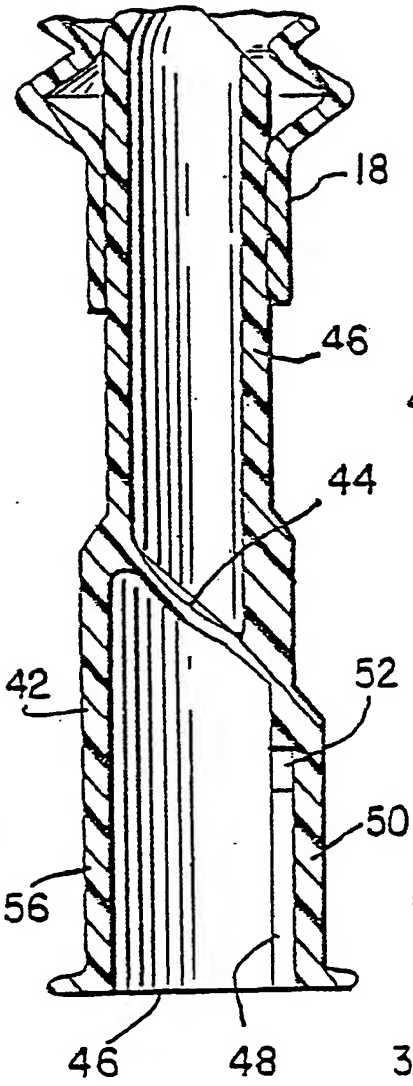
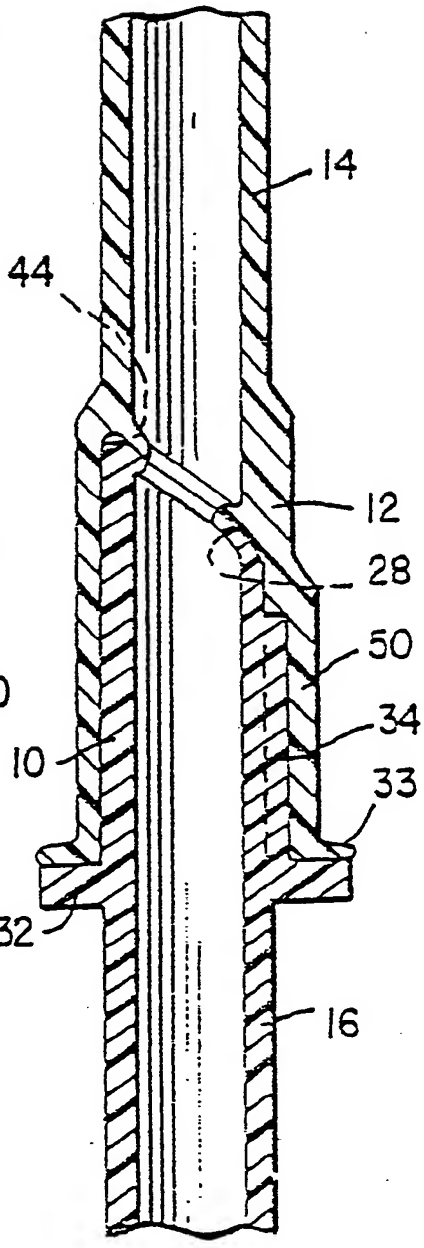


FIG. 6



INTERNATIONAL SEARCH REPORT

International Application No PCT/US 82/00021

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

INT. CL[3]: 8658 3/04 ; A61 M 5/00 247 & 272
U.S. CL : 141/1,98,114,311R,329,330,19,392 128/214R,214.2,

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	141/1,19,98,114,311R,329,330 &392; 128/214R,214.2,247 & 272; 156/250-253,261,272,82,289,304&306; 222/80 ; & 285/31

Documentation Searched other than Minimum Documentation to the Extent that such Documents are included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	U.S. A, 4,019,512 Published 26 April 1977	1-18
X	U.S. A, 4,022,256 Published 10 May 1977	1-18

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IV. CERTIFICATION

Date of the Actual Completion of the International Search [1]	Date of Mailing of this International Search Report [2]
12 March 1982	05 MAY 1982
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	Hunter S. Bell

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